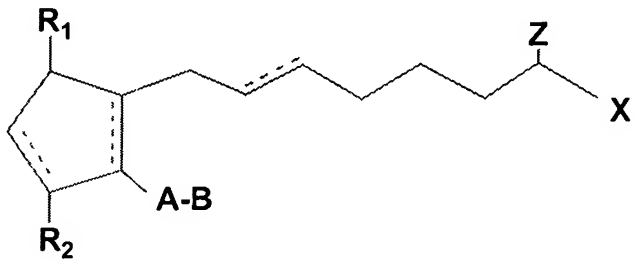
REMARKS

The claims at issue are claims 1-10 and 12-15.

The present invention is method of converting gray hair of the beard or scalp to the original pigment in hair follicles of a human in need thereof which comprises administering to said human a pharmaceutical composition comprising an effective amount of a compound represented by formula I



wherein the dashed bonds represent a single or double bond which can be in the cis or trans configuration, A is an alkylene or alkenylene radical having from two to six carbon atoms, which radical may be interrupted by one or more oxa radicals and substituted with one or more hydroxy, oxo, alkyloxy or akylcarboxy groups wherein said alkyl radical comprises from one to six carbon atoms; B is a cycloalkyl radical having from three to seven carbon atoms, or an aryl radical, selected from the group consisting of hydrocarbyl aryl and heteroaryl radicals having from four to ten carbon atoms wherein the heteroatom is selected from the group consisting of nitrogen, oxygen and sulfur atoms; X is $-N(R^4)_2$ wherein R^4 is selected from the group consisting of hydrogen, a lower alkyl radical having from one to six carbon atoms,

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R^5-C- and R^5-O-C-, wherein R^5 is a lower alkyl radical having from one to six carbon atoms; Z is =O; one of R_1 and R_2 is =O, -OH or a -O(CO)R_6 group, and the other one is -OH or -O(CO)R_6, or R_1 is =O and R_2 is H, wherein R_6 is a saturated or unsaturated acyclic hydrocarbon group having from 1 to about 20 carbon atoms, or -(CH_2)mR_7 wherein m is 0 or an integer of from 1 to 10, and R_7 is cycloalkyl radical, having from three to seven carbon atoms, or a hydrocarbyl aryl or heteroaryl radical, as defined above or a pharmacologically acceptable acid addition salt thereof. The compounds represented by this formula are known as prostamides because of the amide group at the 1-position of the molecule. The 1-amide provides these compounds with a different biological activity then the chemically-related prostaglandins, which have a carboxylic acid, or ester thereof, at the 1-position.

Regarding the Examiner's previous rejection of the claims under 35 USC 103(a), it is noted that the Examiner no longer argues that the prostamides used in the method of the instant invention are equivalent to the prostaglandins taught in the prior art.

Regarding the present rejection the Examiner has rejected claims 16 and 17 under 37 CFR 1.75 as being substantial duplicates of claims 13 and 14, respectively. This rejection is now moot because claims 16 and 17 have been cancelled.

The Examiner has rejected claims 1-10 and 12-17 under 35 USC 103(a) as being unpatentable over the article New Drugs of 2001 (J Amer. Pharm. Association 2002) in view of US Patent Number 5290562 (the "562 Patent").

In particular, the Examiner argues that the article "discloses two new drugs for glaucoma,

bimatoprost and travoprost of which the former is within the scope of the instant claims." The Examiner goes on to argue that the "article teaches that the compound bimatoprost is useful in reducing the intraocular pressure (page 2). However, the side effects of the compound included among others, darkening of eyelashes, eyelash growth and pigmentation (page 3). Thus, the compound of the instant invention is known for increasing the pigmentation and darkening of hairs (eye lashes). The article also teaches 0.3% bimatoprost (claim 2) as a solution (claim 9)." But, in conclusion, the Examiner states that the article fails to teach the claimed method. That is, the Examiner notes that the article teaches a method for the treatment of glaucoma; not the treatment of grey hair.

The Examiner states that while the above article fails to teach the claimed method per se, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ bimatoprost for increasing pigmentation or darkening hair (eyelash or beard or scalp hair) because the compound bimatoprost is known to increase pigmentation.

The Examiner uses the '562 Patent to teach that it is known that one may use a ***tyrosine derivative*** to increase the melanin synthesis in UV damaged skin. The Examiner also asserts that this patent teaches that pigment activity in the scalp is also increased by a ***tyrosine derivative***. The Examiner concludes that it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ the composition containing bimatoprost, of "New Drugs 2001" article, for retarding the appearance of grey hair in a mammal in need thereof because" '562 teaches that increasing or stimulating melanin synthesis improves the retardation of grey hair together with increasing the melanin pigment."

In response, the applicant wishes to point out that the treatment of glaucoma is a medical procedure carried out by an ophthalmologist, while dyeing grey hair is the work of a cosmetician or the person with grey hair and certainly, not the ophthalmologist, unless he is treating his own hair. This distinction is important when considering the prior art the Examiner is using to find the claimed

invention obvious, because the invention must be obvious to a person of ordinary skill in the art to which the invention pertains. "The hypothetical 'person having ordinary skill in the art' to which the claimed subject matter pertains would, of necessity have the capability of understanding the scientific and engineering principles applicable to the pertinent art." *Ex parte Hiyamizu*, 10 USPQ2d 1393, 1394 (Bd. Pat. App. & Inter. 1988) (See MPEP 21451.03.) It is believed that the one of ordinary skill in the art, most closely related to the method of the present invention, would be the cosmetician. This person would not be familiar with drugs used to treat glaucoma. In fact, the Examiner is attempting to combine two nonanalogous arts, i.e. the cosmetic and pharmaceutical arts. This is not proper for an obviousness rejection under 35 USC 103.

In the last amendment, to further distinguish the claimed invention from the prior art, the applicant amended the claims to point out that the method of the invention is primarily directed toward the treatment of grey hair of the scalp or beard of a human. This limitation further distinguished the invention, as claimed, from the prior art, which disclosed the changes in the color of eyelashes, only. (Note the applicant also offered various articles to point out that eyelashes are not equivalent to scalp hair. See **Hormone Research** 2000;54:243-250 and **Hair Science: How and Why Hair Grows.)**

In response to this amendment, the Examiner turns to applicant's own specification and argues that a careful review of the instant specification on page 7, lines 10-18 states: "As used herein, gray hair includes hair associated with the scalp, eyebrows, eyelids, beard, and other areas of the skin of animals, e.g. humans". Thus, the ability of bimatoprost in converting gray hair to original pigment is not dependent upon the hair location (beard or scalp or eyelash)."

Here the Examiner is using the applicant's own specification to reject the claims, even though the specification is not a part of the prior art. (See MPEP 2129 which states that, "even if labeled as "prior art," the work of the same inventive entity may not be considered prior art against the claims unless it falls under one of the statutory categories. *Id.*; see also *Reading & Bates Construction Co. v. Baker Energy Resources Corp.*, 748 F.2d 645, 650, 223 USPQ 1168,

1172 (Fed. Cir. 1984) ("[W]here the inventor continues to improve upon his own work product, his foundational work product should not, without a statutory basis, be treated as prior art solely because he admits knowledge of his own work. It is common sense that an inventor, regardless of an admission, has knowledge of his own work.").

Consequently, the examiner must determine whether the subject matter identified as "prior art" is applicant's own work, or the work of another. In the absence of another credible explanation, examiners should treat such subject matter as the work of another."). To further support the applicant's contention that the applicant's own specification is not prior art, see also, Noelle v. Lederman, 355 F.3d 1343, 69 USPQ2d 1508 (Fed. Cir. 2004) and MPEP **2163**.

Thus, the Examiner's use of the present specification to dismiss applicant's evidence that eyelashes and scalp or beard hair are not the same is not proper and when the Examiner argues that " the ability of bimatoprost in converting gray hair to original pigment is not dependent upon the hair location (beard or scalp or eyelash)", he is correct, because that is the applicants invention.

It is believed that the claims, as presently amended, are in condition for allowance. The Examiner is asked to reconsider and withdraw the outstanding rejection and pass the claims to issue.

Respectfully submitted,

RJ Baran

Robert J. Baran, Reg. No. 25,806
Attorney of Record
2372 S.E. Bristol, Suite B
Newport Beach, California 92660
Tel: (949) 851-5010
Fax: (949) 752-1925

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